

REMARKS

Claims 1-15 are currently pending in this application, claims 16-41 having been previously cancelled from prosecution. In the Responsive Amendment received by the US Patent Office on August 27, 2004, Applicants inadvertently omitted the previously cancelled claims 16-41 in the list of claims. In response to the Notice of Non-Compliant Amendment mailed on October 5, 2004, Applicants have amended the previously submitted Responsive Amendment (received on August 27, 2004) to include these inadvertently omitted and previously cancelled claims 16-41. In all other respects, this Response to Notice of Non-Compliant Amendment is identical in all respects to the Responsive Amendment received on August 27, 2004. Applicants respectfully request favorable consideration of the present application in light of the amendments to the specification and claims and the following remarks.

Specification

Although not specifically objected to in the Office Action, the specification has been amended to correct typographical errors and improve its overall wording. In particular, the paragraphs beginning on page 7 line 22 and ending on page 8 line 4 have been replaced with improved paragraphs. No new matter has been entered with this amendment. The specification is believed to be in proper form for allowance.

Claim Rejections – 35 USC 102(b) - Forber

Claims 1-3, 5-6, 8 and 14-15 were rejected under 35 USC 102(b) as being anticipated by US Patent No. 5,733,294 to Forber et. al. Applicants respectfully traverse this rejection as set forth below.

In order for a reference to anticipate the present claimed invention under 35 U.S.C. 102(b), it must be shown that each and every element of the claim can be found in the

reference. If it can be shown that one element of the claim is missing or not met by the cited reference, the rejection must be withdrawn as inappropriate.

Claim 1 describes a method of sealing a hole in a body part. The first step involves introducing into the hole a generally cylindrically shaped mesh, wherein the mesh has a generally cylindrically shaped lumen extending between a proximal end and a distal end. The second step involves moving at least of the proximal and distal ends of the mesh at least partially into the lumen such that the lumen expands radially outward against sides of the hole.

Claim 14 describes a method of sealing a hole in a body. The first step involves introducing into the hole a generally cylindrically shaped mesh, wherein the mesh has a generally cylindrically shaped lumen extending between a proximal end and a distal end. The second step involves pushing a proximal end of the mesh at least partially into the lumen such that the mesh expands radially outward against sides of the hole.

Claim 15 describes a method of sealing a hole in a body. The first step involves introducing into the hole a generally cylindrically shaped mesh, wherein the mesh has a generally cylindrically shaped lumen extending between a proximal end and a distal end. The second step involves pulling a distal end of the mesh at least partially into the lumen such that the mesh expands radially outward against sides of hole.

The Forber reference appears to be silent with regard to at least one element found in Claims 1, 14, and 15, such that rejection for anticipation should be withdrawn. First, contrary to the assertion in the Office Action, the Forber reference does not appear to disclose at least one feature common to Claims 1, 14 and 15, namely “*introducing into a hole a generally cylindrically shaped mesh, the mesh having a generally cylindrically shaped lumen extending between a proximal end and a distal end.*” The device disclosed in Forber

is constructed from a memory-shape material (ie. Nitinol) and has a shape likened to “two cones attached end to end,” (Col. 2 lines 11-12 & Figs. 1, 4, & 5e) and alternatively, two annular disks (Col. 5 line 63 & Fig. 6 & 8) or a singular disk with accompanying filaments extending from one end (Col. 6 lines 8-11 & Fig. 9).

The Forber reference also appears to be silent with regard to the claim 1 step of *“moving at least of the proximal and distal ends of the mesh at least partially into the lumen such that the lumen expands radially outward against sides of the hole,”* the claim 14 step of *“pushing a proximal end of the mesh at least partially into the lumen such that the mesh expands radially outward against sides of the hole,”* and finally the claim 15 step of *“pulling a distal end of the mesh at least partially into the lumen such that the mesh expands radially outward against sides of hole.”* The ends of the Forber device are comprised of the band assemblies (best viewed in a number of figures including 1, 3, & 9) which are composed of metals such as platinum or titanium (Col. 3 lines 42-45). The metal composition should make it impossible to turn the ends in on themselves as would be necessary to enter the *interior* of a generally cylindrical lumen (as set forth in claims 1, 14 and 15). Instead, (as viewed in Fig. 1, 4, & 10) as the band assemblies move toward each other, the Forber device changes shape such that the interior bulges around the band assembly. The metal ends however, unable to turn in on themselves, remain on the exterior of the device.

Because Forber fails to teach or disclose at least one claimed feature in each of the independent claims 1, 14, and 15, Applicants respectfully submit that the rejection under 35 USC 102(b) should be withdrawn in favor of an indication of allowance, which is hereby earnestly solicited.

Claims 2-9, being dependant on and further limiting independent Claim 1, should be allowable for the reasons set forth above, as well as the additional limitations they contain.

Claim Rejections – 35 USC 102(e) - Leschinsky

Claim 15 was rejected under 35 USC 102(e) as being anticipated by US Patent No. 5,904,713 to Leschinsky. Applicants respectfully traverse this rejection as set forth below.

Claim 15 describes a method of sealing a hole in a body. The first step involves introducing into the hole a generally cylindrically shaped mesh, wherein the mesh has a generally cylindrically shaped lumen extending between a proximal end and a distal end. The second step involves pulling a distal end of the mesh at least partially into the lumen such that the mesh expands radially outward against sides of hole.

The Leschinsky reference appears to be silent with regard to at least one element found in amended claim 15, such that rejection for anticipation should be withdrawn. Among other voids the Leschinsky reference does *not* appear to disclose the feature of introducing a cylindrically shaped mesh *into the hole*. The graft apparatus of Leschinsky is directed at treating aneurysms which are located within blood vessels. The aneurysm itself is simply a localized widening (dilatation) of an artery or vein typically resulting in a bulge or cavity in the vessel wall. The Leschinsky graft is introduced into the vessel *adjacent* to the hole (bulge or cavity), in effect sealing the hole from the outside, creating a new vessel wall, and isolating the aneurysm. This is in contra-distinction to the cylindrical mesh of the present invention which is introduced *into* the hole and seals the hole along its internal length. This important distinction allows the present invention to be used on holes that are not contained within walled vessels, such as the surgical access hole created during an annulotomy. An added advantage of this feature is that it prevents unwanted substances from entering the interior space of the hole.

The Leschinsky reference also appears to be silent as to the Claim 15 feature of *“pulling a distal end of the mesh at least partially back into the lumen such that the mesh expands radially outwards against sides of the hole.”* The Leschinsky graft apparatus

comprises of a length of graft and fixation devices attached at both the proximal and distal ends. The graft itself is clearly not a mesh element as it is impenetrable to blood (Col. 2 line 50). While it is not entirely clear from the disclosure, in the event that the fixation devices attached to the proximal and distal ends of the graft are a mesh element, pulling the distal cylindrical mesh through a second and proximal cylindrical mesh (as would be the case in Leschinsky) is dissimilar to pulling the distal end of a singular cylindrical mesh into the interior of the lumen as in Claim 15. An important element set forth in Claim 15 is that pulling the distal end of the cylindrical mesh back into an interior portion of the lumen causes the cylindrical mesh to expand radially outward against the sides of the hole. Comparatively, pulling one cylindrical mesh through a separate cylindrical mesh will not cause the mesh to extend radially outwards against the sides of the hole. Moreover, even if the graft apparatus of Leschinsky were a single cylindrical mesh, pulling the distal end completely through the proximal end until the apparatus was inverted (as taught by Leschinsky) would have the effect of returning the mesh back to its original diameter rather than expanding radially outwards against the sides of the hole. Thus, Leschinsky is silent as to this important feature of Claim 15.

Because Leschinsky fails to teach or disclose at least one claimed feature in the independent claim 15, applicants respectfully submit that the rejection under 35 USC 102(e) should be withdrawn in favor of an indication of allowance, which is hereby earnestly solicited.

Claim Rejections – 35 USC 103(c) – Forber in view of Ken

Claims 12 and 13 were rejected under 35 USC 103(c) as being unpatentable over Forber in view of US Patent No. 6,293,960 to Ken. Applicants respectfully traverse this rejection as set forth below.

Claims 12 and 13, being dependant upon and further limiting independent Claim 1,

should be allowed for the reasons set forth above in support of the allowability of Claim 1, as well as the additional features it contains. The Ken reference does not cure the aforementioned deficiencies in what was fairly taught by Forber, such that the rejection of Claims 12 and 13 should also be withdrawn in favor of an indication of allowance, which is hereby earnestly solicited.

Allowable Subject Matter

Applicants wish to thank the Examiner for the allowance of claims 10 and 11, and for the indication of allowability with respect to claims 4, 7, 9, 12 and 13.

CONCLUSION

The foregoing amendment has been submitted to place the present application in condition for allowance. Favorable consideration and allowance of the claims in this application is respectfully requested. In the event that there are any questions concerning this Amendment or the application in general, the Examiner is cordially invited to telephone the undersigned attorney so that prosecution may be expedited.

In the event there are any fees associated with this Response to Notice of Non-Compliant Amendment, the Commissioner is hereby authorized to charge such fees to Deposit Number 50-2040 in the name of NuVasive, Inc (assignee of the subject application), as well as to credit any overpayments.

Respectfully submitted,
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